California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LEGISLATION AND REGULATION COMMITTEE

Legislation Report

NO ACTION

Status Update for Bills with Board Position -

Assembly Bill 320 - Support
Status: Vetoed

Assembly Bill 1826 - Support.
Status: Dead

Assembly Bill 1957 - Oppose
Status: Vetoed
Attachment 1

Assembly Bill 2184 - Support
Status: Chaptered
Attachment 2

Assembly Bill 2660 – Support
Status: Chaptered
Attachment 3

Senate Bill 1149 - Oppose
Status: Vetoed

Senate Bill 1159 – Support
Status: Chaptered
Attachment 4

Senate Bill 1427 - Support
Status: Dead

Senate Bill 1735 - Support
Status: Dead

Status Update for Bills without Board Position

Assembly Bill 30
Status: Chaptered
Attachment 5

Assembly Bill 1960
Status: Vetoed

Assembly Bill 2125
Status: Dead

Senate Bill 1333
Status: Vetoed

Senate Bill 1563
Status: Vetoed

Board Sponsored Legislation

Senate Bill 1307 (Figueroa) and Assembly Bill 2682 (Negrete McLeod)

These bills were signed by the Governor. They implement the board's proposed changes to wholesaler regulation including the imposition of a bond requirement, establishment of a drug pedigree system, increased licensing requirements for nonresident wholesalers, and increased fines for specified wholesale violations.

See Attachment 6 for the text of these measures.

Senate Bill 1913 (Business and Professions Committee)

This bill was signed by the Governor. This bill makes numerous technical and non-controversial changes to pharmacy law.

See Attachment 7 for the text of this measure.

Quarterly Status Report on Committee Goals for 2003-04

For your information, an update of the Committee's progress in accomplishing its strategic objectives is attached to this report (Attachment 8).

Attachment 1

To the Members of the California State Assembly:

I am returning Assembly Bill 1957 without my signature.

A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. We all would like to see low-income uninsured residents have access to more affordable medicines, but measures such as this, over-simplify the complex safety, trade, supply and pricing issues involved in this marketplace. In light of these circumstances, I do not believe AB 1957 will bring the necessary relief to Californians who require assistance in accessing necessary medicines.

In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward "California Rx" that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($47,000 for a family of three) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx. While I am encouraged by the concrete commitments made by some members of the industry, I am disappointed that many companies have not yet stepped up and offered meaningful discounts for this population. Over the next six weeks, I will continue negotiations to secure significant discounts for California's low-income uninsured, and I hope to move forward with a legislative proposal in January 2005 to implement California Rx. If, however, specific companies and the industry as a whole are not willing to provide a real solution to this problem, I will work closely with the State Legislature to develop an approach that guarantees significant reductions in prescription drug prices for California's low-income uninsured residents.

Come January, I will propose legislation that will bring lower-cost prescription drugs to California's most vulnerable residents. I am still hopeful that California Rx will be the vehicle to secure those price reductions, but for a voluntary, negotiated model such as California Rx to work, the drug companies must come forward and negotiate in good faith. I call upon the companies to help solve this problem through California Rx; but if I cannot rely on the good faith negotiations of the industry, I will use all the options at my disposal to secure lower-cost prescription drugs for low-income, uninsured Californians.

For these reasons I am returning this bill without my signature.

Sincerely,

Arnold Schwarzenegger

Attachment 2

Assembly Bill No. 2184

CHAPTER 342

An act to amend Section 4008 of, and to add Section 4119.1 to, the Business and Professions Code, and to amend Sections 1261.5 and 1261.6 of the Health and Safety Code, relating to health facilities.

[Approved by Governor August 27, 2004. Filed with Secretary of State August 30, 2004.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2184, Plescia. Health facilities: pharmacy services: automated drug delivery systems.

Existing law provides for the licensing and regulation by the State Department of Health Services of health facilities, including skilled nursing facilities and intermediate care facilities.

The Pharmacy Law, which provides for the licensing and regulation of the practice of pharmacy, is under the jurisdiction of the California State Board of Pharmacy. The Pharmacy Law prescribes requirements for the dispensing of drugs. Under existing law, anyone who knowingly violates the Pharmacy Law is guilty of a misdemeanor.

Existing law authorizes a pharmacy to furnish dangerous drugs or dangerous devices to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container that is maintained within the facility in accordance with regulations of the department. Existing law establishes circumstances under which drugs may be removed from an automated drug delivery system at a skilled nursing facility or intermediate care facility. Existing law defines an automated drug delivery system as a mechanical system that performs operations and activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs.

This bill would provide that a pharmacy may provide services to a skilled nursing facility or intermediate care facility through the use of an automated drug delivery system that meets certain requirements and the automated drug delivery system need not be located at the same location as the pharmacy. The bill would require that this automated drug delivery system be under the supervision of a licensed pharmacist, would not require that the pharmacist be physically present at the site, and would permit the pharmacist to supervise the system electronically. When a pharmacist releases drugs for removal from the automated drug delivery system for administration to a patient, the bill would prohibit the automated drug delivery system from providing facility staff with

access to drugs different from those released. Because the bill would specify additional requirements under the Pharmacy Law and health facility laws, a violation of which is a crime, the bill would impose a state-mandated local program.

The bill would also correct an erroneous cross-reference.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4008 of the Business and Professions Code is amended to read:

4008. (a) Except as provided by Section 159.5, the board may employ inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter

apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

SEC. 2. Section 4119.1 is added to the Business and Professions Code, to read:

4119.1. (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) Nothing in this section shall be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

SEC. 3. Section 1261.5 of the Health and Safety Code is amended to read:

1261.5. (a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c) or (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4119 of the Business and Professions Code, shall be limited to 24. The State Department of Health Services may limit the number of doses of each drug available to not more than four doses of any separate drug dosage form in each emergency supply.

(b) Any limitations established pursuant to subdivision (a) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs.

SEC. 4. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an ''automated drug delivery system'' means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, ''facility'' means a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy,

accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all users accessing the system and all drugs removed from the system.

(6) When a pharmacist releases drugs for removal from the automated drug delivery system pursuant to paragraph (2), the automated drug delivery system shall not provide facility staff with access to drugs different from those released.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Attachment 3

Assembly Bill No. 2660

CHAPTER 191

An act to amend Sections 4040, 4052, 4060, 4076, and 4111 of the Business and Professions Code, and to amend Section 11150 of the Health and Safety Code, relating to pharmaceuticals.

[Approved by Governor July 23, 2004. Filed with Secretary of State July 23, 2004.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2660, Leno. Prescriptions: issuance by a pharmacist.

Existing law, the Uniform Controlled Substances Act, authorizes a pharmacist in specified circumstances to write or issue a prescription. The Pharmacy Law, which provides for the licensure and regulation by the California State Board of Pharmacy of pharmacy practices, defines a prescription, in part, as being issued by designated healing arts practitioners, not including a pharmacist. The Pharmacy Law prohibits the board from issuing a pharmacy license to, or renewing a pharmacy license of, specified persons, including those who are authorized to write a prescription. A knowing violation of the Pharmacy Law is a misdemeanor offense.

This bill would revise the definition of ''prescription'' to include a drug order issued by a pharmacist pursuant to specified conditions. The bill would also specify that the board is not precluded from issuing or renewing a license for a pharmacy owned or owned and operated by a pharmacist who is authorized to issue a specified drug order.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4040 of the Business and Professions Code is amended to read:

4040. (a) ‘‘Prescription’’ means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1, respectively, or the pharmacist who issues a drug order pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, or 3502.1, by a certified nurse-midwife, nurse practitioner, or physician assistant licensed in this state, or pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) ‘‘Electronic transmission prescription’’ includes both image and data prescriptions. ‘‘Electronic image transmission prescription’’ means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. ‘‘Electronic data transmission prescription’’ means any prescription order, other than an electronic

image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

SEC. 2. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) (A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency

contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(d) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(e) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 3. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a

manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.

SEC. 4. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6

(commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 5. Section 4111 of the Business and Professions Code is amended to read:

4111. (a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

SEC. 6. Section 11150 of the Health and Safety Code is amended to read:

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 of the Business and

Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Attachment 4

Senate Bill No. 1159

CHAPTER 608

An act to amend Sections 4145 and 4147 of, and to repeal Section 4146 of, the Business and Professions Code, to amend Section 11364 of, and to add Chapter 13.5 (commencing with Section 121285) to Part 4 of Division 105 of, the Health and Safety Code, relating to hypodermic needles and syringes.

[Approved by Governor September 20, 2004. Filed with Secretary of State September 20, 2004.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1159, Vasconcellos. Hypodermic needles and syringes.

(1) Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes. Under existing law, a prescription is required to purchase a hypodermic needle or syringe for human use, except to administer adrenaline or insulin.

This bill, subject to authorization by a county or city, would authorize a licensed pharmacist, until December 31, 2010, to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created by the bill to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.

The bill would require a pharmacy that participates in the Disease and Demonstration Project pursuant to county or city authorization to comply with specified requirements, including registering with the local health department. The bill would require the State Department of Health Services, in conjunction with an advisory panel, to evaluate the effects of allowing the sale of hypodermic needles or syringes without prescription, and would require a report to be submitted to the Governor and the Legislature by January 15, 2010. The bill would encourage the State Department of Health Services to seek funding from private and federal sources to pay for the evaluation. The bill would impose various other duties on local health departments, thereby imposing a state-mandated local program. The demonstration program would terminate on December 31, 2010.

Alternatively, the bill would also authorize the sale or furnishing of hypodermic needles or syringes to a person for human use without a

prescription if the person is known to the furnisher and has previously provided the furnisher with a prescription or other proof of a legitimate medical need.

The bill would make it unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school. The bill would make a knowing violation of this prohibition a crime, thereby imposing a state-mandated local program.

(2) Existing law requires a pharmacist to keep detailed records of nonprescription sales of hypodermic needles and syringes.

This bill would delete that requirement.

(3) Existing law prohibits the possession and sale of drug paraphernalia.

This bill, until December 31, 2010, subject to authorization by a county or city, would allow a person to possess 10 or fewer hypodermic needles or syringes if acquired through an authorized source.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement, including the creation of a State Mandates Claims Fund to pay the costs of mandates that do not exceed $1,000,000 statewide and other procedures for claims whose statewide costs exceed $1,000,000.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

(5) This bill would make the operation of its provisions contingent upon the enactment of SB 1362.

The people of the State of California do enact as follows:

SECTION 1. Section 4145 of the Business and Professions Code is amended to read:

4145. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if one of the following requirements is met:

(1) The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate

medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(2) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2010, a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered for the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

(b) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

SEC. 2. Section 4146 of the Business and Professions Code is repealed.

SEC. 3. Section 4147 of the Business and Professions Code is amended to read:

4147. (a) For the purposes of this section, ‘‘playground’’ means any park or outdoor recreational area specifically designed to be used by children that has play equipment installed or any similar facility located on public or private school grounds or county parks.

(b) Any hypodermic needle or syringe that is to be disposed of, shall be contained, treated, and disposed of, pursuant to Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code.

(c) It is unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school.

(d) A person who knowingly violates subdivision (c) is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than two hundred dollars ($200) and not more than two thousand dollars ($2,000), or by imprisonment in a county jail for up to six months, or by both that fine and imprisonment.

(e) Subdivision (c) does not apply to the containment, treatment, and disposal of medical sharps waste from medical care or first aid services rendered on school grounds, nor to the containment, treatment, and

disposal of hypodermic needles or syringes used for instructional or educational purposes on school grounds.

SEC. 4. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within in the city, for the period commencing January 1, 2005, and ending December 31, 2010, subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

SEC. 5. Chapter 13.5 (commencing with Section 121285) is added to Part 4 of Division 105 of the Health and Safety Code, to read:

CHAPTER 13.5. DISEASE PREVENTION DEMONSTRATION PROJECT

121285. (a) The Disease Prevention Demonstration Project, a collaboration between pharmacies and local and state health officials, is hereby authorized for the purpose of evaluating the long-term desirability of allowing licensed pharmacists to furnish or sell nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.

(b) The State Department of Health Services shall evaluate the effects of allowing pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010. The State Department of Health Services is encouraged to seek funding from private and federal sources to pay for the evaluation. The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following:

(1) Hypodermic needle or syringe sharing practice among those who inject illegal drugs.

(2) Rates of disease infection caused by hypodermic needle or syringe sharing.

(3) Needlestick injuries to law enforcement officers and waste management employees.

(4) Drug crime or other crime in the vicinity of pharmacies.

(5) Safe or unsafe discard of used hypodermic needles or syringes.

(6) Rates of injection of illegal drugs.

(c) The State Department of Health Services shall convene an uncompensated evaluation advisory panel comprised of all of the following: two or more specialists in the control of infectious diseases; one or more representatives of the California State Board of Pharmacy; one or more representatives of independent pharmacies; one or more representatives of chain pharmacy owners; one or more representatives of law enforcement executives, such as police chiefs and sheriffs; one or more representatives of rank and file law enforcement officers; a specialist in hazardous waste management from the State Department of Health Services; one or more representatives of the waste management industry; and one or more representatives of local health officers.

(d) In order to furnish or sell nonprescription hypodermic needles or syringes as part of the Disease Prevention Demonstration Project in a county or city that has provided authorization pursuant to Section 4145 of the Business and Professions Code, a pharmacy shall do all of the following:

(1) Register with the local health department by providing a contact name and related information, and certify that it will provide, at the time of furnishing or sale of hypodermic needles or syringes, written information or verbal counseling on all of the following:

(A) How to access drug treatment.

(B) How to access testing and treatment for HIV and hepatitis C.

(C) How to safely dispose of sharps waste.

(2) Store hypodermic needles and syringes so that they are available only to authorized personnel, and not openly available to customers.

(3) In order to provide for the safe disposal of hypodermic needles and syringes, a registered pharmacy shall provide one or more of the following options:

(A) An onsite safe hypodermic needle and syringe collection and disposal program.

(B) Furnish or make available for purchase mail-back sharps disposal containers authorized by the United States Postal Service that meet applicable state and federal requirements, and provide tracking forms to verify destruction at a certified disposal facility.

(C) Furnish or make available for purchase personal sharps disposal containers that meet state and federal standards for disposal of medical waste.

(e) Local health departments shall be responsible for all of the following:

(1) Maintaining a list of all pharmacies within the local health department's jurisdiction that have registered under the Disease Prevention Demonstration Project.

(2) Making available to pharmacies written information that may be provided or reproduced to be provided in writing or orally by the pharmacy at the time of furnishing or the sale of nonprescription hypodermic needles or syringes, including all of the following:

(A) How to access drug treatment.

(B) How to access testing and treatment for HIV and hepatitis C.

(C) How to safely dispose of sharps waste.

(f) As used in this chapter, ''sharps waste'' means hypodermic needles, syringes, and lancets.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because in that regard this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

However, notwithstanding Section 17610 of the Government Code, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code. If the statewide cost of the claim for reimbursement does not exceed one million dollars ($1,000,000), reimbursement shall be made from the State Mandates Claims Fund.

SEC. 7. This act shall become operative only if Senate Bill 1362 of the 2003–04 Regular Session is enacted and becomes effective on or before January 1, 2005.

O

Attachment 5

Assembly Bill No. 30

CHAPTER 573

An act to amend Sections 11161, 11162.1, and 11190 of the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 18, 2004. Filed with Secretary of State September 18, 2004.]

LEGISLATIVE COUNSEL'S DIGEST

AB 30, Richman. Controlled substances: Schedule II.

(1) Existing law provides that no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless it complies with specified requirements, one of which is to issue prescriptions for Schedule II controlled substances on either triplicate prescription blanks issued by the Department of Justice or prescription forms for controlled substance prescriptions obtained from security printers approved by the Board of Pharmacy. Existing law provides that the provision requiring the Department of Justice to issue triplicate prescription blanks to practitioners shall remain operative until July 1, 2004, and shall be repealed on January 1, 2005.

This bill would provide that the provision requiring the Department of Justice to issue triplicate prescription blanks to practitioners shall instead remain operative until November 1, 2004.

(2) Existing law provides that a prescriber designated by a licensed health care facility who orders controlled substance prescription forms for use by prescribers when treating patients in that facility shall maintain in that facility for 3 years a record containing specified information of the prescribers to whom controlled substance prescription forms are issued.

This bill would provide that forms printed by a computerized prescription generation system shall not be subject to these recordkeeping provisions and may, but are not required to, contain specified information.

(3) Existing law provides that for each prescription for a Schedule II controlled substance that is dispensed by a practitioner in his or her office or place of practice, the prescriber shall record and maintain specified information, including the pharmacy prescription number, license number, and federal controlled substance registration number.

This bill would no longer require the practitioner who dispenses a Schedule II controlled substance in his or her office or place of practice

to record and maintain the pharmacy prescription number, license number, and federal controlled substance registration number.

(4) The bill would declare that it is to take effect immediately as an urgency statute.

The people of the State of California do enact as follows:

SECTION 1. Section 11161 of the Health and Safety Code, as amended by Section 4 of Chapter 406 of the Statutes of 2003, is amended to read:

11161. (a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate unless a practitioner orally, electronically, or in writing requests a larger amount, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable. Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor.

(b) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks in the practitioner's possession at a time set in the order and shall direct the Department of Justice to withhold prescription blanks from the practitioner. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (c) and (f) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(c) The order provided by subdivision (b) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a

preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(d) The defendant may elect to challenge the order issued under subdivision (b) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (c) and any other evidence otherwise admissible at the preliminary examination.

(e) If the practitioner has not moved to vacate the order issued under subdivision (b) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (b) shall be vacated.

(f) Notwithstanding subdivision (e), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (b).

(g) This section shall become inoperative on November 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 2. Section 11161 of the Health and Safety Code, as added by Section 5 of Chapter 406 of the Statutes of 2003, is amended to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks or controlled substance prescription forms in the practitioner's possession at a time set in the order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks or controlled substance prescription forms with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

SEC. 3. Section 11162.1 of the Health and Safety Code is amended to read:

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive ‘‘void’’ pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word ‘‘void’’ shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words ‘‘California Security Prescription.’’

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermo-chromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity checkoff boxes shall be printed on the form and the following quantities shall appear:

1-24
25-49
50-74
75-100
101-150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall either (A) contain a statement printed on the bottom of the prescription blank that the ‘‘Prescription is void if more than one controlled substance prescription is written per blank’’ or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the ‘‘Prescription is void if the number of drugs prescribed is not noted.’’

(9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

(10) A check box indicating the prescriber’s order not to substitute.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address,

category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued, which record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber and shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) This section shall become operative on July 1, 2004.

SEC. 4. Section 11190 of the Health and Safety Code, as added by Section 28 of Chapter 406 of the Statutes of 2003, is amended to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance is administered or prescribed.

(c) (1) For each prescription for a Schedule II controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) NDC (National Drug Code) number of the controlled substance dispensed.

(D) Quantity of the controlled substance dispensed.

(E) ICD-9 (diagnosis code), if available.

(F) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in either hardcopy or electronic form.

(d) This section shall become operative on July 1, 2004, and shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 5. Section 11190 of the Health and Safety Code, as added by Section 29 of Chapter 406 of the Statutes of 2003, is amended to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) NDC (National Drug Code) number of the controlled substance dispensed.

(D) Quantity of the controlled substance dispensed.

(E) ICD-9 (diagnosis code), if available.

(F) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in either hardcopy or electronic form.

(d) This section shall become operative on January 1, 2005.

SEC. 6. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of

Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to effectuate the smooth transition by prescribers of Schedule II controlled substances from the use of triplicate prescription forms to the use of controlled substance prescription forms issued by security printers, and to make related changes, it is necessary for this act to take effect immediately.

O

Attachment 6

Senate Bill No. 1307

CHAPTER 857

An act to amend Sections 4054, 4165, and 4166 of, to amend, repeal, and add Sections 4053, 4059.5, 4081, 4100, 4105, 4160, 4163, 4163.6, 4164, 4196, 4301, 4305.5, 4331, and 4400 of, to add Sections 4022.5, 4034, 4084, 4085, 4086, 4126.5, 4163.5, and 4168 to, to add and repeal Sections 4053.1 and 4169 of, and to repeal and add Section 4162 of, the Business and Professions Code, relating to drugs.

[Approved by Governor September 29, 2004. Filed with Secretary of State September 29, 2004.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, Figueroa. Wholesalers and manufacturers of dangerous drugs and devices.

(1) Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law requires that dangerous drugs or dangerous devices be dispensed only by licensed pharmacists and only to certain persons or entities. Existing law provides certain exemptions from this requirement for manufacturers, veterinary food-animal drug retailers, and wholesalers, including those that employ sufficient qualified supervision by a person who possesses a certificate of exemption. Existing law also requires the board to take action against a licensee who is guilty of unprofessional conduct, as defined. Existing law makes a violation of the Pharmacy Law a crime.

This bill would revise the list of persons to whom a pharmacy may furnish dangerous drugs. The bill would also revise the exemption provisions related to manufacturers, veterinary food-animal drug retailers, and wholesalers, and would change the certificate of exemption requirement to a requirement of licensure as a designated representative, as defined. The bill would require a wholesaler to keep track of excessive purchases of dangerous drugs by a pharmacy that primarily or solely dispenses those drugs to patients of long-term care facilities, and would make the clearly excessive furnishing of dangerous drugs to that pharmacy by a wholesaler unprofessional conduct. The bill would make other related changes.

This bill would, on and after January 1, 2007, require a pedigree, as defined, to accompany each distribution of a dangerous drug, except if the compliance date is extended. It would, on and after that date, prohibit a wholesaler or pharmacy from selling, trading, or transferring a

dangerous drug without a pedigree, and would prohibit a wholesaler or pharmacy from acquiring a dangerous drug without receiving a pedigree.

(2) Existing law prohibits a person from acting as a wholesaler of dangerous drugs or devices without a license.

This bill would require dangerous drugs or dangerous devices to be acquired from a person authorized by law to possess or furnish them. The bill would exempt a licensed drug manufacturer that only ships drugs of its own manufacture from the provisions governing wholesalers, except for the prohibition against furnishing dangerous drugs or devices to an unauthorized person.

(3) Existing law imposes certain licensing and registration requirements on out-of-state manufacturers and wholesalers doing business in this state, and on their principals and agents.

This bill would delete these requirements.

(4) Existing law requires any manufacturer who sells or transfers a dangerous drug or dangerous device into this state or who receives a dangerous drug or dangerous device from a person in this state to, upon request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer. Existing law makes a manufacturer who fails or refuses to comply with that request subject to a citation and a fine, an order of abatement, or both.

This bill instead would apply these provisions to a wholesaler licensed by the board. The bill would delete the provision that makes the failure or refusal to comply with a request subject to a citation and a fine, an order of abatement, or both. The bill would require a wholesaler to submit a surety bond of $100,000, or an equivalent means of security, for all sites to be licensed.

(5) The bill would prohibit a county or municipality from issuing a business license for an establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

The bill would prohibit a person or entity from purchasing, trading, selling, or transferring a dangerous drug or device under specified circumstances, including if he or she knew, or reasonably should have known, the drug or device was adulterated or misbranded. The bill would make a violation of those provisions subject to a specified fine.

The bill would specify to whom a pharmacist may furnish dangerous drugs.

(6) The bill would make its provisions operative on January 1, 2006, except as specified.

(7) Because a violation of the requirements and prohibitions created by this bill would be a crime, the bill would impose a state-mandated local program.

(8) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

(9) This bill would become operative only if AB 2682 is also enacted and becomes effective on or before January 1, 2005.

(10) This bill would incorporate additional changes in Sections 4059.5 and 4081 of the Business and Professions Code proposed by SB 1913, to be operative only if SB 1913 and this bill are both enacted and take effect, and this bill is enacted last.

The people of the State of California do enact as follows:

SECTION 1. Section 4022.5 is added to the Business and Professions Code, to read:

4022.5. (a) ''Designated representative'' means an individual to whom a license has been granted pursuant to Section 4053.

(b) ''Designated representative-in-charge'' means a designated representative or a pharmacist who is the supervisor or manager of a wholesaler or veterinary food-animal drug retailer.

(c) This section shall become operative on January 1, 2006.

SEC. 3. Section 4034 is added to the Business and Professions Code, to read:

4034. (a) ''Pedigree'' means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.

(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(d) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(e) This section shall become operative on January 1, 2007.

SEC. 6. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler if the board shall find that sufficient, qualified supervision is employed by the veterinary food-animal drug retailer or wholesaler to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual employed by a veterinary food-animal drug retailer or wholesaler may apply for an exemption from Section 4051. In order to obtain and maintain that exemption, the individual shall meet the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of state and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may, by regulation, require training programs to include additional material.

(6) The board shall not issue a certificate of exemption until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption on its premises.

(d) Only a pharmacist or an individual in possession of a certificate of exemption shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative before January 1, 2006, amends or repeals that date.

SEC. 7. Section 4053 is added to the Business and Professions Code, to read:

4053. (a) Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a designated representative to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become operative on January 1, 2006.

SEC. 8. Section 4053.1 is added to the Business and Professions Code, to read:

4053.1. (a) Certificates of exemption issued or renewed pursuant to Section 4053 prior to January 1, 2005, shall remain valid until their expiration date or until January 1, 2007, whichever date is earlier.

(b) Individuals in possession of a current and valid certificate of exemption shall be issued a license as a designated representative if the individual satisfies the requirements of Section 4053 and pays the fee required by subdivision (i) of Section 4400.

(c) This section shall become inoperative and be repealed on January 1, 2007, unless a later enacted statute, that becomes operative on or before December 31, 2006, amends or repeals that date.

SEC. 9. Section 4054 of the Business and Professions Code is amended to read:

4054. Section 4051 shall not apply to a manufacturer or wholesaler that provides dialysis drugs and devices directly to patients.

SEC. 10. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or

delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drug or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. Any person or entity receiving delivery of any dangerous drugs or dangerous devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 10.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the

hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating

to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 11. Section 4059.5 is added to the Business and Professions Code, to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or physical therapist acting within the scope of his or her license. A person or entity receiving delivery of any dangerous drugs or dangerous devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) This section shall become operative on January 1, 2006.

SEC. 11.5. Section 4059.5 is added to the Business and Professions Code, to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall become operative on January 1, 2006.

SEC. 12. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 12.5. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 13. Section 4081 is added to the Business and Professions Code, to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare

and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

SEC. 13.5. Section 4081 is added to the Business and Professions Code, to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

SEC. 14. Section 4084 is added to the Business and Professions Code, to read:

4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give

notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.

(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated or counterfeit, a board inspector shall remove the tag or other marking.

(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.

(d) For the purposes of this article ''counterfeit'' shall have the meaning defined in Section 109905 of the Health and Safety Code.

(e) For the purposes of this article ''adulterated'' shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

SEC. 15. Section 4085 is added to the Business and Professions Code, to read:

4085. (a) It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or dangerous device without permission of the board.

(b) When a board inspector has reasonable cause to believe, that the embargo will be violated, a board inspector may remove the embargoed dangerous drug or dangerous device from the premises.

SEC. 16. Section 4086 is added to the Business and Professions Code, to read:

4086. (a) If a dangerous drug or dangerous device is alleged to be adulterated or counterfeit, the board shall commence proceedings in the superior court in whose jurisdiction the dangerous drug or dangerous device is located, for condemnation of the dangerous drug or dangerous device.

(b) If the court finds that an embargoed dangerous drug or dangerous device is adulterated or counterfeit, the dangerous drug or dangerous device shall, after entry of the judgment, be destroyed at the expense of the claimant or owner, under the supervision of the board. All court costs and fees and all reasonable costs incurred by the board in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, shall be paid by the claimant or owner of the dangerous drug or dangerous device.

(c) A superior court of this state may condemn any dangerous drug or dangerous device pursuant to this article. In the absence of an order, the dangerous drug or dangerous device may be destroyed under the supervision of the board who has the written consent of the owner, his or her attorney, or authorized representative. If the board cannot ascertain ownership of the dangerous drug or dangerous device within

30 days of establishing an embargo, the board may destroy the dangerous drug or dangerous device.

SEC. 17. Section 4100 of the Business and Professions Code is amended to read:

4100. (a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, every pharmacist, intern pharmacist, technician, or exemptee shall notify the executive officer of the board of the change of address or change of name.

(b) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 18. Section 4100 is added to the Business and Professions Code, to read:

4100. (a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, or designated representative shall notify the executive officer of the board of the change of address or change of name.

(b) This section shall become operative on January 1, 2006.

SEC. 19. Section 4105 of the Business and Professions Code is amended to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the exemptee, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 20. Section 4105 is added to the Business and Professions Code, to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) This section shall become operative on January 1, 2006.

SEC. 23. Section 4126.5 is added to the Business and Professions Code, to read:

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, ''common control'' means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, ''long-term care facility'' shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

SEC. 24. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee-in-charge. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A

wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, ''exemptee-in-charge'' means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) A drug manufacturer licensed by the Food and Drug Administration or pursuant to Section 111615 of the Health and Safety Code that only ships dangerous drugs or dangerous devices of its own manufacture is exempt from this section.

(g) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 25. Section 4160 is added to the Business and Professions Code, to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) A drug manufacturer licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to

exceed the annual fee for renewal of a license to conduct business as a wholesaler.

(g) This section shall become operative on January 1, 2006.

SEC. 29. Section 4162 of the Business and Professions Code is repealed.

SEC. 30. Section 4162 is added to the Business and Professions Code, to read:

4162. (a) (1) An applicant for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 31. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.

(b) No person shall acquire dangerous drugs or dangerous devices from a person not authorized by law to possess or furnish those dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 32. Section 4163 is added to the Business and Professions Code, to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) A wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

(e) This section shall become operative on January 1, 2007.

SEC. 33. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 33.1. Section 4163.6 is added to the Business and Professions Code, to read:

4163.6. If the Legislature determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of dangerous drugs within the state, the Legislature may extend the date for compliance with the requirement

for a pedigree for pharmacies set forth in Section 4163 until January 1, 2009.

SEC. 34. Section 4164 of the Business and Professions Code is amended to read:

4164. (a) All wholesalers licensed by the board and all manufacturers who distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 35. Section 4164 is added to the Business and Professions Code, to read:

4164. (a) A wholesaler licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent. Each wholesaler shall have the tracking system required by this subdivision in place no later than January 1, 2006.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, ‘‘preferential or contract prices’’ means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

(e) This section shall become operative on January 1, 2006.

SEC. 36. Section 4165 of the Business and Professions Code is amended to read:

4165. A wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

SEC. 37. Section 4166 of the Business and Professions Code is amended to read:

4166. (a) Any wholesaler that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

SEC. 38. Section 4168 is added to the Business and Professions Code, to read:

4168. A county or municipality may not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For purposes of this section, an ‘‘establishment’’ is the licensee’s physical location in California.

SEC. 39. Section 4169 is added to the Business and Professions Code, to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 40. Section 4169 is added to the Business and Professions Code, to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall become operative on January 1, 2007.

SEC. 41. Section 4196 of the Business and Professions Code is amended to read:

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, an exempt person, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or exemptee shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, ''exemptee-in-charge'' means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 42. Section 4196 is added to the Business and Professions Code, to read:

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license

from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) This section shall become operative on January 1, 2006.

SEC. 43. Section 4301 of the Business and Professions Code is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured

by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction

shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 44. Section 4301 is added to the Business and Professions Code, to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating

controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly

excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code.

(t) This section shall become operative on January 1, 2006.

SEC. 45. Section 4305.5 of the Business and Professions Code is amended to read:

4305.5. (a) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee, and who continues to operate the licensee in the absence of a pharmacist or an exemptee approved for that location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer.

(c) Any pharmacist or exemptee who takes charge of, or acts as manager of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 46. Section 4305.5 is added to the Business and Professions Code, to read:

4305.5. (a) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated

representative-in-charge. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of the designated representative-in-charge, and who continues to operate the licensee in the absence of the designated representative-in-charge for that location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer.

(c) A designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall become operative on January 1, 2006.

SEC. 47. Section 4331 of the Business and Professions Code is amended to read:

4331. (a) Any person who is neither a pharmacist nor an exemptee and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) Any person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) Any person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 48. Section 4331 is added to the Business and Professions Code, to read:

4331. (a) A person who is neither a pharmacist nor a designated representative and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) A person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) This section shall become operative on January 1, 2006.

SEC. 49. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars ($75) and may be

increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).

(i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(*l*) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred

seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

(w) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 50. Section 4400 is added to the Business and Professions Code, to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for a designated representative license issued pursuant to Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer designated representative, for whom the fee shall be one hundred dollars ($100).

(i) The fee for a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer designated representative license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) The fee for a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(*l*) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

(w) This section shall become operative on January 1, 2006.

SEC. 51. This act shall become operative only if Assembly Bill 2682 is also enacted and becomes effective on or before January 1, 2005.

SEC. 52. Sections 10.5 and 11.5 of this bill incorporate amendments to Section 4059.5 of the Business and Professions Code proposed by both this bill and SB 1913. Sections 10.5 and 11.5 shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2005, (2) each bill amends Section 4059.5 of the Business and Professions Code, and (3) this bill is enacted after SB 1913, in which case Sections 10 and 11 of this bill shall not become operative.

SEC. 53. Sections 12.5 and 13.5 of this bill incorporate amendments to Section 4081 of the Business and Professions Code proposed by both this bill and SB 1913. Sections 12.5 and 13.5 shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2005, (2) each bill amends Section 4081 of the Business and Professions Code, and (3) this bill is enacted after SB 1913, in which case Sections 12 and 13 of this bill shall not become operative.

SEC. 54. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Assembly Bill No. 2682

CHAPTER 887

An act to amend, repeal, and add Section 4043 of, to add and repeal Section 4162.5 of, and to repeal and add Section 4161 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

[Approved by Governor September 29, 2004. Filed with Secretary of State September 29, 2004.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2682, Negrete McLeod. Pharmacy: out-of-state wholesalers.

The Pharmacy Act provides for licensing and regulation of manufacturers and wholesalers of prescription drugs and devices by the California State Board of Pharmacy and makes a violation of its provisions a crime. Existing law requires out-of-state manufacturers and wholesalers of prescription drugs and devices selling or distributing those drugs and devices in this state to obtain an out-of-state dangerous drugs and devices distributor's license from the board, unless they sell or distribute only through a licensed wholesaler.

This bill would delete these requirements applicable to out-of-state manufacturers and wholesalers of prescription drugs and devices on January 1, 2006. The bill would instead, on and after January 1, 2006, require a nonresident wholesaler, as defined, that ships, mails, or delivers dangerous drugs or dangerous devices in this state to obtain a nonresident wholesaler's license from the board. The bill would, on and after January 1, 2006, require, until January 1, 2011, a nonresident wholesaler to submit a surety bond of $100,000, or an equivalent means of security for each place of business owned or operated by the nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in California. Because this bill would require additional persons to pay fees to the board to obtain a license, it would result in the deposit of additional revenue in the Pharmacy Board Contingent Fund, a continuously appropriated fund, and would thereby make an appropriation.

Because a violation of the Pharmacy Act is a crime, the bill would impose a state-mandated local program by revising the definition of a crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would become operative only if SB 1307 is also enacted and becomes effective on or before January 1, 2005.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4043 of the Business and Professions Code is amended to read:

4043. (a) ''Wholesaler'' means and includes every person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or out-of-state distributor, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 2. Section 4043 is added to the Business and Professions Code, to read:

4043. (a) ''Wholesaler'' means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall become operative January 1, 2006.

SEC. 3. Section 4161 of the Business and Professions Code is repealed.

SEC. 4. Section 4161 is added to the Business and Professions Code, to read:

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale shall be considered an out-of-state distributor.

(b) An out-of-state distributor shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by an out-of-state distributor from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of an out-of-state distributor license, or within 30 days of a change in the following information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners, if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) An out-of-state distributor shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) An out-of-state distributor wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) An out-of-state distributor shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for an out-of-state distributor license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew an out-of-state distributor license until the out-of-state distributor identifies an exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.

(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A

temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as an out-of-state distributor.

(*l*) The license fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003–04 Regular Session, including any subsequent amendment thereto, shall not be considered an out-of-state distributor for purposes of this section.

(n) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 4.5. Section 4161 is added to the Business and Professions Code, to read:

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.

(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003–04 Regular Session, including any subsequent amendment thereto, shall not be considered a nonresident wholesaler for purposes of this section.

(n) This section shall become operative January 1, 2006.

SEC. 5. Section 4162.5 is added to the Business and Professions Code, to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten

million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 6. This act shall become operative only if Senate Bill 1307 is also enacted and becomes effective on or before January 1, 2005.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Attachment 7

Senate Bill No. 1913

CHAPTER 695

An act to amend Sections 28, 1054, 1274, 2041, 2082, 2087, 2107, 2274, 2317, 2420, 2423, 2462, 2532.6, 2570.14, 2902, 2915.7, 2936, 3750.5, 4005, 4030, 4101, 4114, 4115, 4200, 4207, 4409, 4980.395, 4990.4, 4996.18, 4996.20, 4996.26, and 18629 of, to amend and repeal Section 5810 of, to amend, repeal, and add Sections 4059.5 and 4081 of, to add Sections 1005, 2475.1, 2514, 2571, 3702.7, 3719.5, 3769.3, 4026.5, 4068, 4107, 4127.7, 4170.5, 4208, and 4209 to, to add and repeal Section 4200.1 of, and to repeal Section 2265 of, the Business and Professions Code, to amend Section 13401 of the Corporations Code, and to amend Sections 11159.1 and 11207 of the Health and Safety Code, relating to professions.

[Approved by Governor September 22, 2004. Filed with Secretary of State September 22, 2004.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1913, Committee on Business and Professions. Professions.

(1) Existing law provides for the licensing and regulation of psychologists, clinical social workers, and marriage and family therapists. Existing law requires a person applying for licensure as a psychologist, clinical social worker, or marriage and family therapist on and after January 1, 1987, to have completed specified coursework or training in child abuse assessment and reporting from certain types of institutions.

This bill would revise the types of educational institutions from which the training may be obtained.

(2) Existing law provides for the regulation of clinical laboratories. Existing law requires a clinical laboratory to send to persons submitting cytological samples for evaluation information letters on all cases of dysplasia, and requires that, when a clinical lab determines that an abnormality of dysplasia has been identified for a patient for whom the lab earlier reported a normal finding, all previous cytologic slides on that patient be reexamined by the lab.

This bill would instead state that documentation is required for high-grade squamous intraepithelial lesions, adenocarcinoma, or other malignant neoplasm.

(3) Existing law, the Medical Practice Act, provides for the licensing and regulation of physicians and surgeons by the Division of Licensing and the Division of Medical Quality, respectively, in the Medical Board

SEC. 25. Section 3769.3 is added to the Business and Professions Code, to read:

3769.3. (a) Notwithstanding any other provision, the board may, by stipulation with the affected licensee, issue a public reprimand, after it has conducted an investigation, in lieu of filing or prosecuting a formal accusation.

(b) The stipulation shall contain the authority, grounds, and causes and circumstances for taking such action and by way of waiving the affected licensee's rights, inform the licensee of his or her rights to have a formal accusation filed and stipulate to a settlement thereafter or have the matter in the statement of issues heard before an administrative law judge in accordance with the Administrative Procedures Act.

(c) The stipulation shall be public information and shall be used as evidence in any future disciplinary or penalty action taken by the board.

SEC. 26. Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; pertaining to the sale of drugs by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.

(d) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 27. Section 4026.5 is added to the Business and Professions Code, to read:

4026.5. ''Good standing'' means a license issued by the board that is unrestricted by disciplinary action taken pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 28. Section 4030 of the Business and Professions Code is amended to read:

4030. ''Intern pharmacist'' means a person issued a license pursuant to Section 4208.

SEC. 29. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or

country to which the drugs or devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the drugs or devices are to be delivered shall include, but not be limited to, determining that the recipient of the drugs or devices is authorized by law to receive the drugs or devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

SEC. 29.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user’s agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the

hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating

to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 29.7. Section 4059.5 is added to the Business and Professions Code, to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall become operative on January 1, 2006.

SEC. 30. Section 4068 is added to the Business and Professions Code, to read:

4068. (a) Notwithstanding any provision of this chapter, a prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply:

(1) The hospital pharmacy is closed and there is no pharmacist available in the hospital.

(2) The dangerous drug is acquired by the hospital pharmacy.

(3) The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.

(4) The hospital pharmacy retains the dispensing information and, if the drug is a schedule II or schedule III controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.

(5) The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

(6) The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.

(7) The prescriber shall ensure that the label on the drug contains all the information required by Section 4076.

(b) The prescriber shall be responsible for any error or omission related to the drugs dispensed.

SEC. 31. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee-in-charge had no knowledge, or in which he or she did not knowingly participate.

SEC. 31.5. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate,

license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 31.7. Section 4081 is added to the Business and Professions Code, to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

SEC. 32. Section 4101 of the Business and Professions Code is amended to read:

4101. (a) A pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.

(b) An exemptee-in-charge of a wholesaler or veterinary food drug-animal retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.

SEC. 33. Section 4107 is added to the Business and Professions Code, to read:

4107. The board may not issue more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy. For the purposes of this subdivision, ''premises'' means a location with its own address and an independent means of ingress and egress.

SEC. 34. Section 4114 of the Business and Professions Code is amended to read:

4114. (a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board.

(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

SEC. 35. Section 4115 of the Business and Professions Code is amended to read:

4115. (a) Notwithstanding any other provision of law, a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of, a pharmacist.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (a) except under the direct supervision and control of a pharmacist.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the direct supervision and control of a pharmacist. Any pharmacy that employs a pharmacy technician to perform tasks specified in subdivision (a) shall

do so in conformity with the regulations adopted by the board pursuant to this subdivision.

(e) (1) No person shall act as a pharmacy technician without first being registered with the board as a pharmacy technician as set forth in Section 4202.

(2) The registration requirements in paragraph (1) and Section 4202 shall not apply during the first year of employment for a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(f) (1) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.

(2) This subdivision shall not apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. Notwithstanding the exemption in this subdivision, the requirements of subdivisions (a) and (b) shall apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental

Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (b) and (f), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

SEC. 36. Section 4127.7 is added to the Business and Professions Code, to read:

4127.7. On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:

(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

SEC. 37. Section 4170.5 is added to the Business and Professions Code, to read:

4170.5. (a) Veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school may dispense and administer dangerous drugs and devices and controlled substances from a common stock.

(b) The veterinary teaching hospital shall designate a pharmacist to be responsible for ordering the drugs for the common stock and the designated pharmacist-in-charge shall be professionally responsible to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, and dispensing occur in a manner that is consistent with the promotion and protection of the health and safety of the public.

(c) The veterinary teaching hospital's pharmacist-in-charge shall develop policies, procedures, and guidelines that recognize the unique relationship between the institution's pharmacists and veterinarians in the control, management, dispensation, and administration of drugs.

(d) The board may inspect a veterinary teaching hospital dispensing or administering drugs pursuant to this section.

SEC. 38. Section 4200 of the Business and Professions Code is amended to read:

4200. (a) The board may license as a pharmacist any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

SEC. 39. Section 4200.1 is added to the Business and Professions Code, to read:

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the Multi-State Pharmacy Jurisprudence Examination for California four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California.

(f) From January 1, 2004, to July 1, 2006, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, 2006, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

(g) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.

SEC. 40. Section 4207 of the Business and Professions Code is amended to read:

4207. (a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

SEC. 41. Section 4208 is added to the Business and Professions Code, to read:

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

SEC. 42. Section 4209 is added to the Business and Professions Code, to read:

4209. (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

SEC. 43. Section 4409 of the Business and Professions Code is amended to read:

4409. At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4110 or a pharmacist license is renewed

pursuant to Section 4401, the pharmacy or pharmacist may make a contribution of at least twenty-five dollars ($25), to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program established pursuant to Article 2 (commencing with Section 128198) of Chapter 3 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be paid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section 128198.5 of the Health and Safety Code.

SEC. 44. Section 4980.395 of the Business and Professions Code is amended to read:

4980.395. (a) A licensee who began graduate study prior to January 1, 2004, shall complete a three-hour continuing education course in aging and long-term care during his or her first renewal period after the operative date of this section and shall submit to the board evidence, acceptable to the board, of the person's satisfactory completion of the course.

(b) The course shall include, but is not limited to, the biological, social, and psychological aspects of aging.

(c) A person seeking to meet the requirements of subdivision (a) of this section may submit to the board a certificate evidencing completion of equivalent courses in aging and long-term care taken prior to the operative date of this section, or proof of equivalent teaching or practice experience. The board, in its discretion, may accept that certification as meeting the requirements of this section.

(d) The board may not renew an applicant's license until the applicant has met the requirements of this section.

(e) Continuing education courses taken pursuant to this section shall be applied to the 36 hours of approved continuing education required in Section 4980.54.

(f) This section shall become operative on January 1, 2005.

SEC. 45. Section 4990.4 of the Business and Professions Code is amended to read:

4990.4. ''Accredited school of social work,'' within the meaning of this chapter, is a school that is accredited by the Commission on Accreditation of the Council on Social Work Education.

SEC. 46. Section 4996.18 of the Business and Professions Code is amended to read:

4996.18. (a) A person who wishes to be credited with experience toward licensure requirements shall register with the board as an associate clinical social worker prior to obtaining that experience. The application shall be made on a form prescribed by the board and shall be

to a certificate of registration issued by the governmental agency regulating the profession as herein provided and that in its practice or business designates itself as a professional or other corporation as may be required by statute. However, any professional corporation or foreign professional corporation rendering professional services by persons duly licensed by the Medical Board of California or any examining committee under the jurisdiction of the board, the Osteopathic Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the California Architects Board, the Court Reporters Board of California, the Board of Behavioral Sciences, the Speech-Language Pathology and Audiology Board, or the Board of Registered Nursing shall not be required to obtain a certificate of registration in order to render those professional services.

(c) ''Foreign professional corporation'' means a corporation organized under the laws of a state of the United States other than this state that is engaged in a profession of a type for which there is authorization in the Business and Professions Code for the performance of professional services by a foreign professional corporation.

(d) ''Licensed person'' means any natural person who is duly licensed under the provisions of the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act to render the same professional services as are or will be rendered by the professional corporation or foreign professional corporation of which he or she is or intends to become, an officer, director, shareholder, or employee.

(e) ''Disqualified person'' means a licensed person who for any reason becomes legally disqualified (temporarily or permanently) to render the professional services that the particular professional corporation or foreign professional corporation of which he or she is an officer, director, shareholder, or employee is or was rendering.

SEC. 52. Section 11159.1 of the Health and Safety Code is amended to read:

11159.1. An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under the provisions of Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code.

Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

SEC. 53. Section 11207 of the Health and Safety Code is amended to read:

11207. (a) No person other than a pharmacist as defined in Section 4036 of the Business and Professions Code or an intern pharmacist, as defined in Section 4030 of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.

(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

SEC. 54. Sections 29.5 and 29.7 of this bill incorporate amendments to Section 4059.5 of the Business and Professions Code proposed by both this bill and SB 1307. Sections 29.5 and 29.7 shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2005, (2) each bill amends Section 4059.5 of the Business and Professions Code, and (3) this bill is enacted after SB 1307, in which case Section 29 of this bill shall not become operative.

SEC. 55. Sections 31.5 and 31.7 of this bill incorporate amendments to Section 4081 of the Business and Professions Code proposed by both this bill and SB 1307. Sections 31.5 and 31.7 shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2005, (2) each bill amends Section 4081 of the Business and Professions Code, and (3) this bill is enacted after SB 1307, in which case Section 31 of this bill shall not become operative.

SEC. 56. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Attachment 8

Legislation and Regulation Committee
Strategic Plan Update for October 2004

Goal 3:	**Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.**
Outcome:	**Improve the health and safety of Californians.**

Objective 3.1:	**Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.**
Measure:	**100 percent successful enactment of promoted legislative changes**
Tasks:	1. Secure extension of board's sunset date. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 3. Sponsor legislation to add enforcement options for non-compliance issues. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. **Advocacy: AB 320, AB 1826, AB 1960, AB 2184, AB 2660, AB 2682, SB 1159, AB 1196, SB 1427, SB 1563, SB 1735, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774** **Technical Assistance: AB 262, AB 746, AB 1196, AB 1957, AB 2125, SB 151, SB 175, SB 292, SB 361, SB 490, SB 545, SB 774, SB 907, SB 1149, SB 1333** 6. Sponsor clean-up language to B & P Code section 4312. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. **Public meetings held on March 27, 2003 and September 11, 2003. Public meeting held on March 30, 2004.** 8. Sponsor legislation to strengthen consumer protections in wholesale transactions. **Completed 9/29/2004 – Chapters 857 and 887, Statutes of 2004.**

	9. Sponsor legislation to address licensing issues related to the UC Davis Veterinary Medical Teaching Hospital. **Governor signed SB 1913 September 22, 2004.**

Objective 3.2:	**Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.**
Measure:	**Percentage successful enactment of promoted regulatory changes**
Tasks:	1. Strengthen standards for compounding sterile injectable drug products. **Completed. Regulation effective October 29, 2004.** 2. Authorize the executive officer the authority to issue citations and fines. **Completed. Regulation effective October 11, 2003.** 3. Eliminate the clerk typist ratio. **Completed. Regulation effective October 3, 2004.** 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. **Completed. Regulation effective October 2, 2004.** 5. Update pharmacy self-assessment form. 6. Allow central filling by hospital pharmacies. **Completed. Regulation effective October 22, 2004.** 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. **Completed. Regulation effective October 22, 2004.** 8. Modify patient notification provision of the quality assurance regulation to require notification only if the error results in the medication being administerd to the patient or a clinically significant delay in therapy. **Completed. Regulation effective October 22, 2004.** 9. Require pharmacies using a common electronic file to adopt policies to ensure confidentiality of patient information. **Completed. Regulation effective October 22, 2004.** 10. Update pharmacy technician regulations to conform to SB 361. **Completed. Regulation effective October 22, 2004.** 11. Update pharmacist licensure regulations to conform to SB 361. **Completed. Regulation effective October 22, 2004.** 12. Complete a Section 100 filing to clean up regulations in conformity with recent legislation.

Objective 3.3:	**Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.**
Measure:	**Number of areas of pharmacy law reviewed**
Tasks:	1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. **Completed – Chapter 250, Statutes of 2003 (SB 175)** 3. Evaluate group dispensing by prescribers. **August 2003 - Draft legislation developed in concert with the Medical Board. Awaiting board action.** 4. Evaluate pharmacist intern statutes and regulations. **December 2003 – Draft legislation and regulations prepared and presented to the Licensing Committee.** **January 2004 – Draft legislation and regulations approved by the board.** **February 2004 – Rulemaking noticed on approved regulations.** **March 2004 – Statutory provisions introduced in SB 1913.** **Governor signed SB 1913 on September 22, 2004.**